

PATENT COOPERATION TREATY

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From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/L2007/000893

International filing date (day/month/year)
16.07.2007

Priority date (day/month/year)
16.07.2006

International Patent Classification (IPC) or both national classification and IPC
INV. A61F2/00

Applicant
CONTIPI LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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this opinion

see form
PCT/ISA/210

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 66-68

because:

☒ the said international application, or the said claims Nos. 66-68 relate to the following subject matter which does not require an international search (*specify*):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 66-68

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:
- ☒ paid additional fees.
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☐ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos.

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>21,22,44-48</u>
	No: Claims	<u>1-20,23-43,49-65</u>
Inventive step (IS)	Yes: Claims	<u>21,22,44-48</u>
	No: Claims	<u>1-20,23-43,49-65</u>
Industrial applicability (IA)	Yes: Claims	<u>1-20,23-65</u>
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item III.

Claims 66-68 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to novelty, inventive step and industrial applicability (Article 34(4)(a)(I) PCT).

Re Item IV.

The following groups of claims:

- 1-20,23-43,49-65: A system for treating urinary incontinence comprising an apparatus and an applicator coupled to said apparatus for facilitating insertion of the apparatus into the vagina; the apparatus comprises a node, a support section attached to the node and adapted for providing urethral support and an anchoring section attached to said apparatus opposite the support section and adapted for resisting movement of said apparatus.
- 21-22,44: A method for preserving shelf life and performance characteristics of a urinary incontinence treating device
- 45-48: An apparatus for treating urinary incontinence comprising: a plurality of rods, each characterised by a proximal section, a midsection and a distal section; an anchor base and a support base adapted to engage and retain each rod at the proximal section and midsection respectively; and an expansion mechanism comprising a hub and a spoke for each rod wherein each spoke is adapted at each end thereof to engage and retain a distal section of a rod and the hub is adapted to contact a neck of the support base

define three different inventions. The reasons are the following:

The first group of claims intends to define an apparatus to be inserted inside the vagina for treating urinary incontinence that is not large, uncomfortable and intrusive avoiding causing irritation or soreness of the vagina. To distend the vaginal wall, the defined apparatus needs to be flexible to allow it to extend into at least two of the three planar subsections that define the nominal curvature of the vagina. An associated applicator avoiding the need of a doctor to place the apparatus is also defined.

The second group of claims intends to define a method and an applicator for preserving shelf life and performance characteristics of a urinary incontinence treating device. It seems that the method and the applicator could be applied to any apparatus to treat female urinary incontinence. Moreover, it seems that keeping at least a support section of the device in a substantially un-compressed state preserves its shelf life and performance characteristics.

The third group of claims defines an apparatus provided with an expansion mechanism. Apparently the expansion mechanism enables the defined apparatus to better adapt to the morphology of the vagina.

These three groups of claims do not seem not to define the same technical features. In fact, no correspondence (they are neither the same nor similar) between the defined technical features is envisaged. Moreover, each of them seem to intend to solve different problems. In conclusion, they do not appear to show a common inventive concept.

Re Item V.

Reference is made to the following document:

D1: WO 2005/087154 A (CONTIPI LTD [IL]; ZIV ELAN [IL]) 22 September 2005
(2005-09-22)

FIRST INVENTION

1. Although claims 1,16,23,32,36 have been draft as separate independent claims, they appear to relate to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject matter. The reasons are the following:

Due to the multiple embodiments described in the present application and to the lack of reference signs placed in parentheses helping to identify the features of the claims, the following interpretation to the subject matter defined in multiple independent claims 1,16,23,32,36 is given:

- i) Independent claim 1 seems to refer to the embodiment disclosed in figs 4A-4C.
- ii) Independent claim 16 seems to define the same embodiment as independent claim 1 where it differs by adding the feature defining that the defined subject matter (apparatus) comprises a support section suitable to be tensioned; as described in page 19 of the description, lines 15,16, support arms (414) can be flexible. Therefore they are suitable to be tensioned; consequently the subject matter defined in independent claim 16 appears to define the same subject matter of independent claim 1.
- iii) Independent claim 23 defines a node and two poles connected to the node where the two poles are defined as a result to be achieved (providing anchoring and supporting to the apparatus during urinary incontinence) without providing the technical features necessary to achieve the desired result; as described in page 17, lines 17-27, the apparatus is defined as being divided in three parts; a node, an anchoring section and a support section. The described subject matter seems therefore to define the same subject matter of the previous independent claims.
- iv) Independent claim 32 is also defined in terms of a result to be achieved (the apparatus is adapted to render urinary incontinence in any orientation) without providing the technical features necessary to achieve the desired result. As described in page 17, lines 13-16, the terms "anchoring" and "supporting" are for ease of reference; both can be used to provide "anchoring" and/or "support". It seems therefore that the apparatus as defined in independent claim 1 can therefore treat

urinary incontinence whether is in the vagina first inserted with arms 412 or with arms 414. Consequently the subject matter defined in independent claim 32 seems to be the same as the defined in the previous dependent claims.

- v) Independent claim 36 also seems to define a plurality of arms or connected to a node which allows for flexibility of the apparatus in all aspects and axes as defined in the description in page 18, lines 24-27. The defined node seems therefore to be the pivot point defined in claim 36. Consequently, independent claim 36 seems to define the same subject matter of the previous independent claims.

The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of protection.

Hence, claims 1,16,23,32,36 do not meet the requirements of Article 6 PCT.

Due to the above mentioned multiplicity of independent claims seeking to define more or less the same invention in different ways, it seems not feasible to perform a substantive examination on all the claims.

Although also not clear, independent claim 1 seems best to define the idea underlying to the present application. The substantive examination is therefore being based on claim 1 and subsequent dependent claims.

2. Independent claim 1 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

Furthermore, the above-mentioned lack of clarity notwithstanding, the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT, and therefore the criteria of Article 33(1) PCT are not met. The reasons are the following:

Document D1, which is considered the closest prior art, discloses an apparatus for treating urinary incontinence comprising a node (108); a support section (110) attached to

said node and adapted for providing urethral support; and an anchoring section (106) attached to said node opposite the support section and adapted for resisting movement of said apparatus.

3. Dependent claims 2-15,40-43,63-65 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (see passages in the search report).

SECOND INVENTION

4. In the light of the documents cited in the search report, it seems that the subject-matter as claimed in independent claims 21,44 meets the criteria mentioned in Article 33(1) PCT, i.e. it appears to be novel, involve an inventive step and to be industrially applicable. The reasons are the following:

With relation to the applicator disclosed in D1 (see page 16, lines 1-16; fig.10A), the applicator of the present application, by not compressing the incontinence treating device prior to its application, spares it with storage stress preserving its shelf life.

THIRD INVENTION

5. In the light of the documents cited in the search report, it seems that the subject-matter as claimed in independent claim 45 meets the criteria mentioned in Article 33(1) PCT, i.e. it appears to be novel, involve an inventive step and to be industrially applicable. The reasons are the following:

Document D1, which represents the closest prior art, discloses an apparatus for treating urinary incontinence comprising: A plurality of rods (614) characterised by proximal, mid and distal sections; an anchor base (608) and an expansion mechanism

(800) comprising a head (804) (see page 14, lines 6-32; figs. 6A-6C, 8A-8C).

The subject-matter of claim 45 therefore differs from this known apparatus for treating urinary incontinence in that the apparatus defined in the claim also includes a support base to engages the rods and the expansion mechanism instead of a head, includes a hub and a plurality of spokes, each adapted to engage and retain a distal section of each. The subject matter of claim 45 is therefore new.

The problem to be solved by the present invention may therefore be regarded as hoe to reduce manufacturing costs contributing to the ability to provide different sizes of devices by making possible the use different combination of expansion mechanism/anchor bases.

The solution proposed in claim 44 of the present application seems to involve an inventive step (Article 33(3) PCT) for the following reasons: Providing tubing that is separate from the expanding mechanism and by providing tubing that both define the anchor and support portions seems to solve the posed problem. An apparatus for treating urinary incontinence having a similar structure or having a structure that solves the same problem having a different structure seems not to be present in the art. The subject matter of claim 45 seems to be therefore inventive.

Re Item VII.

6. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

7. The requirements of Rule 6.3(b) PCT are not met. The independent claim is not properly cast in the two-part form, with those features which in combination are part of the prior art acknowledged by the applicant being placed in the preamble (Rule 6.3(b)(I)PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii)PCT).

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8. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).